

PUBLICATION OF THE REVISED NIH GRANTS POLICY STATEMENT (REV. 12/03): POLICY CHANGES, CLARIFICATIONS, AND ENHANCEMENTS

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National Institutes of Health
(<http://www.nih.gov>)

The National Institutes of Health (NIH) is pleased to announce the publication of the revised NIH Grants Policy Statement (NIHGPS, rev. 12/03). The NIHGPS (12/03) is applicable to all NIH grants and cooperative agreements with budget periods beginning on or after December 1, 2003. This revision supersedes, in its entirety, the NIH Grants Policy Statement (03/01) as a standard term and condition of award. However, the March 2001 NIHGPS continues to be the standard term and condition for all NIH grants and cooperative agreements with budget periods that began between March 1, 2001 and November 30, 2003.

The NIHGPS provides both up-to-date policy guidance that serve as NIH standard terms and conditions of awards for grants and cooperative agreements, and extensive guidance to individuals that are interested in NIH grants.

The NIHGPS (rev. 12/03) incorporates NIH policy changes since March 2001, public policy changes, policy clarifications, as well as document enhancements. Sections of the revised policy statement have been rewritten to provide clarity; however, the overall policies in these sections have not changed. The document is available in the following electronic formats: HTML and PDF
http://grants.nih.gov/grants/policy/nihgps_2003/index.htm. Links to the 10/98 and 3/01 NIHGPS will remain the same.

NIH will publish interim grants policy changes through the issuance of NIH Guide Notices. Each change will be described, including its applicability and effective date; and the necessary language to implement it as a term or condition of award provided.

Policy changes that are implemented with the 12/03 NIHGPS include:

- o Closely related work: the option for grantees to pursue prior approval to account for multiple projects under a single cost objective has been eliminated. NIH will now apply the relatedness provision of OMB Circular A-21 (C., 4., d., (3)) to all NIH recipients which states if a specific cost can not be reasonably allocated to a specific project; it can be charged to any of the benefiting projects on any reasonable basis.

- o Cost transfers: policy now states that transfers of costs from one project to another or from one competitive segment to the next solely to cover cost overruns are unallowable.

- o Cost overruns: included a definition to the glossary that states: "Any amount charged in excess of the Federal share of costs for the project period (competitive segment)."

Below are examples of NIH policy changes that have occurred since March 2001. Please note that the list below should not be considered all-inclusive; therefore, please refer to the NIH Guide for Grants and Contracts for details on other changes since March 2001 <http://grants.nih.gov/grants/policy/notices.htm>.

- o Expanded Authorities: Application of expanded authorities as a standard term and condition to all NIH awards.

- o Examples of the latest changes in the application submission policies:

- o NIH will continue to accept no more than two revised applications after the submission of the original application; however, the two year limitation has been eliminated;

- o Resubmission of Application policy changed to allow grantees to resubmit unfunded applications as new applications in the following instances: 1) unsuccessful applications for an RFA can be resubmitted as a new investigator-initiated application 2) previously unsuccessful investigator-initiated applications can be resubmitted in response to an RFA as a new application, and

- 3) unfunded applications that are reviewed for one research grant mechanism may be resubmitted for a different grant mechanism and should be prepared as a new application.

- o Data Sharing: Implementation of the NIH data-sharing policy.

- o Just-in-Time procedures: Expanded to include option to submit IACUC approval.

- o NRSA Section Highlights:

- o In accordance with the amendment of the Public Health Service Act, NIH renamed the National Research Service Awards to the Ruth L. Kirschstein National Research Service Awards;

- o Includes the regulatory changes of NRSA part-time training;

- o Audit: Threshold for A-133 audits has increased from \$300,000 to \$500,000 for fiscal years ending on or after 12/31/2003.

Public Policy Changes that are discussed in the 12/03 NIHGPS:

- o Stem Cell Research
- o USA PATRIOT Act
- o Public Health Security and Bioterrorism Preparedness and Response Act of 2002
- o HIPAA Privacy Rule

Policy Clarifications since March 2001:

- o Clinical Practice Compensation (Institutional Base Salary): Compensation may be considered in the institutional base salary as long as all criteria are met: 1) clinical practice must be guaranteed by the university, 2) clinical practice must be reported on the university's appointment form and paid by the university, and 3) clinical practice effort must be included and accounted for in the university's effort reporting.
- o Key Personnel: Expanded definition to describe the contribution of key personnel as "measurable" whether or not salaries are requested. Zero percent effort and "as needed" are not acceptable for individuals that the grantee identifies as key personnel.
- o PI Eligibility: Elaborated on eligibility criteria for certain mechanisms/programs, no change in policy.
- o A discussion on the unallowability of patent costs has been added to the NIHGPS. The policy now states that Invention, Patent, or Licensing Costs are unallowable as either direct or F&A costs because the creation of intellectual property is not a requirement of NIH grant awards. Such costs include licensing or option fees, attorney's fees for preparing or submitting patent application, patent maintenance, or recordation of patent-related information.
- o Consortium Written Agreements: Outlined that it is the responsibility of the grantees to include applicable requirements of the policy statement in their written agreements and highlighted that agreements must also include a reference to the financial conflict of interest policy, intellectual property, and data sharing requirements.

Document Enhancements:

- o NIH Grants Policy Statement and the PHS 398 application glossaries have been merged, where appropriate.
- o Other Support Policy: Previously located in the PHS 398 application has been included in the NIH Grants Policy Statement.
- o Glossary included in a table format.
- o Select Items of Cost section included in a table format.

- o Bayh-Dole Inventions reporting requirements are now included in a table format.
- o Cross Referencing Roles with eRA: NIH Grants Policy Statement role titles have been cross-referenced with the NIH eRA role titles, e.g.: authorized organizational official (also known as the signing official).
- o Abbreviations and acronyms: are used throughout the policy statement without parenthetical; therefore, readers should refer to the master list to identify unfamiliar terms abbreviations and/or acronyms.
- o Index included.

ADDITIONAL INQUIRIES

Additional questions about the NIHGPS may be directed to the NIH Division of Grants Policy at (301) 435-0949 or the Grants Management Specialist that is identified on the NIH Notice of Grant Award.

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